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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/269,897	04/02/1999	KATSUMI AOYAGI	4047	1769

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EXAMINER	
ZEMAN, ROBERT A	
ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 08/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/269,897	AOYAGI ET AL.	
	Examiner	Art Unit	
	Robert A. Zeman	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 May 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *4,11,12,37,38 and 41* is/are pending in the application.

4a) Of the above claim(s) *12* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *4,11,37,38 and 41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 5-13-2005 has been entered.

The amendment filed on 5-13-2005 is acknowledged. Claims 11, 37 and 41 have been amended. Claims 4, 11-12, 34, 37-38 and 41 are pending. Claim 12 remains withdrawn from consideration as being drawn to a nonelected invention. Claims 4, 11, 34, 37-38 and 41 are currently under examination.

Claim Rejections Withdrawn

The rejection of claims 4, 11, 34, 37-38 and 41 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement is withdrawn in lieu of the rejection set forth below.

The rejection of claims 11, 37 and 41 under 35 U.S.C. 112, second paragraph, as being rendered vague and indefinite by method steps (1) and (2) is withdrawn in light of the amendment thereto. As amended steps (1) and (2) are now linked by claim language.

Claims 11, 37 and 41 under 35 U.S.C. 112, second paragraph, as being rendered vague and indefinite by the use of the phrase "reaction buffer" is withdrawn. The term reaction buffer is limited to a solution consisting of guanidine hydrochloride, HCL, Triton X 100 and Tween 20 and wherein the reaction buffer consists of 100 mM sodium phosphate buffer, pH 7.3, containing 0.15 M NaCl, 1% BSA, 0.5% Casein-Na, 0.05% Tween 20 and 1 M Tris (as defined on page 48 of the specification).

New Grounds of Rejection

35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 4, 11, 34, 37-38 and 41 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods of detecting HCV in a biological sample by treating said sample with a "treatment solution" and a "reaction buffer" wherein said "treatment solution" inactivates antibodies present in the sample and consists of guanidine hydrochloride, HCL, Triton X 100 and Tween 20 and wherein the reaction buffer consists of 100 mM sodium phosphate buffer, pH 7.3, containing 0.15 M NaCl, 1% BSA, 0.5% Casein-Na, 0.05% Tween 20 and 1 M Tris (as defined on page 48 of the specification), does not reasonably provide enablement for methods of detecting HCV utilizing treatment solutions or reaction buffers other than those set forth above or any methods for detecting HBV. The specification does not enable

any person skilled in the art to which it pertains, or with which it is most nearly connected, to make/use the invention commensurate in scope with these claims.

The instant claims are drawn to methods of detecting HCV or HBV in a biological sample by treating said sample with a "treatment solution" wherein said "treatment solution" inactivates antibodies present in the sample (see step 1 of claimed methods). Said sample is then subjected to an immunoassay that utilizes an antibody probe after the treated sample is added to a reaction buffer.

The specification gives no guidance as to what combination of components, other than those set forth above, would result in a treatment solution that would inactivate the endogenous antibodies present in the biological sample (step 1 of the claimed methods) but not inactivate the antibody probe subsequently used in the immunoassay (step 2 of the claimed methods). Moreover, the specification is silent as to what, other than those components set forth on page 48 of the specification, constitutes a "reaction buffer". The specification is equally silent on which antibody probes, if any, would be impervious to the inactivating properties of the claimed "treatment solution". Applicant has argued "Applicant has been able to detect an antigen of HCV and HBV with a high degree of sensitivity". However, contrary to that assertion, only one working example (example 10) utilizes both a reaction solution and a reaction buffer. While the skill in the art of immunology, chemistry and protein chemistry is high, one of skill in the art would not be able to contemplate what combination of treatment solution components, reagent buffer components and antibody probe (other than those set forth above) would meet the limitations of the claimed methods since the antibody probe (which must remain functional in order to be used to detect viral antigens in the immunoassay) and the endogenous antibodies

(which must be inactivated) are exposed to the identical conditions. Since, one of skill in the art would not readily be able to predict the effects of a given solution (i.e. that the solution inactivated the endogenous antibodies present in the sample but not inactivate any antibody probe), he/she would not be able to make the treatment solution or reaction buffer (other than those set forth above) needed to perform the claimed method without undue experimentation. Consequently, the specification is only enabling for methods of detecting HCV in a biological sample by treating said sample with a "treatment solution" and a "reaction buffer" wherein said "treatment solution" inactivates antibodies present in the sample and consists of guanidine hydrochloride, HCL, Triton X 100 and Tween 20 and wherein the reaction buffer consists of 100 mM sodium phosphate buffer, pH 7.3, containing 0.15 M NaCl, 1% BSA, 0.5% Casein-Na, 0.05% Tween 20 and 1 M Tris (as defined on page 48 of the specification). It should be noted that the concentrations of solution components in HBV and HCV solutions differ (see Examples 4, 5, 6, 10 and 14). Moreover, the specification discloses no examples utilizing the combination of a "treatment solution" and a "reaction buffer". The only Example drawn to HBV utilizes a "treatment solution" only. Consequently, the specification is not enabling for any method of detecting HBV.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A. Zeman whose telephone number is (571) 272-0866. The examiner can normally be reached on Monday- Thursday, 7am -5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov.

Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

ROBERT A. ZEMAN
PATENT EXAMINER
August 3, 2005